# Message Text

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PAGE 01 TOKYO 04652 230801Z
ACTION OES-07

INFO OCT-01 EA-12 ISO-00 HEW-06 OPR-02 /028 W
----------098880 230810Z /13
P 230749Z MAR 78
FM AMEMBASSY TOKYO
TO SECSTATE WASHDC PRIORITY 6376

UNCLAS TOKYO 04652

FOR OES/APT/BMP

DEPT PASS TO FDA/BUREAU OF DRUGS

E.O. 11652: N/A
TAGS: OTRA, OCON, TBIO, JA
SUBJECT: VISIT OF FDA REPRESENTATIVES--APRIL 1978

REF: STATE 71555 AND PREVIOUS

1. EMBASSY WELCOMES VISIT OF FDA REPRESENTATIVES TO JAPAN APRIL 5-18. ARRANGEMENTS FOR FDA-PAB MEETING APRIL 10-12, FDA REPS' VISITS TO PHARMACEUTICAL FIRMS IN TOKYO AND OSAKA APRIL 13, AND THEIR MEETING WITH REPS OF U.S. DRUG MANUFACTURERS IN JAPAN DURING THEIR STAY HERE ARE BEING MADE BY MHW AND EMBASSY.

2. RE PROPOSED AGENDA FOR FDA-PAB MEETING, PAB HAS FOLLOWING POINTS TO MAKE: (1) TO PAB, AGENDA ITEM V (POST-MARKETING SURVEILLANCE PROJECT) SEEMS TO REQUIRE FURTHER CLARIFICATION, ESPECIALLY IN TERMS OF SUBSTANCE OF DISCUSSION; (2) PAB WOULD LIKE TO ADD ONE MORE ITEM TO AGENDA: SAFETY OF DRUGS AND COSMETICS. TO BE DISCUSSED UNDER THIS ITEM ARE (A) CARCINOGENECITY OF CLOSIBRETE, (B) CARCINOGENECITY OF DAPSON, OR 4,4-SULFONYL DIANILINE, (C) CARCINOGENECITY OF HAIR
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DYE, (D) CARCINOGENECITY OF N-NITROSO COMPOUNDS, ESP. INTERNAL REACTIONS OF DRUGS AND NITROUS ACIDS, AND (E) CARCINOGENECITY OF N-NITROSO DIETHANOLAMINE IN COSMETICS.

3. TOKYO DRUG FIRM TO BE VISITED BY HALPERIN AND BYERS WILL BE SANKYO AND OSAKA FIRM TO BE VISITED BY BYERS WLL BE TAKEDA.

4. MHW HAS RECOMMENDED A FEMALE INTERPRETER EXPERIENCED IN INTERNATIONAL MEDICAL CONFERENCES. SHE IS KEIKO SATO FROM JAPAN CONVENTION SERVICES. COST OF HIRING HER FOR THREE-DAY MEETING ESTIMATED AT YEN 180,000 (ABOUT DOLS 782 AT CURRENT CONVERSION RATE OF 230/1). EMBASSY WOULD APPRECIATE RECEIVING FISCAL DATA IF FDA WISHES TO HIRE HER.

5. SCICOUNS LOOKS FORWARD TO SEEING HALPERIN AND BYERS AGAIN MORNING OF APRIL 10. CONCERNING MEETING WITH U.S. DRUG MANUFACTURERS, HE HAS APPROACHED AMERICAN CHAMBER OF COMMERCE IN JAPAN TO SEE IF A COLLECTIVE MEETING UNDER ACCJ AUSPICES COULD BE ARRANGED IN PRINCIPLE. THIS WOULD SAVE TIME OF VISITORS AND AVOID ANY EX PARTE PROBLEMS THAT MIGHT POTENTIALLY EXIST IF ANY OF MANUFACTURERS HAVE ACTIONS AGAINST THEM BY FDA. REACTION OF ACCJ NOT YET KNOWN. WOULD APPRECIATE FDA REACTION TO THIS APPROACH. MANSFIELD

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NNN

Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014

# Message Attributes

**Automatic Decaptioning:** X
**Capture Date:** 01 jan 1994
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**Draft Date:** 23 mar 1978
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